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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,984	07/21/2004	Adreas F. Schaub	2923-763	3383

6449 7590 11/16/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
11/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,984	SCHAUB, ADREAS F.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/31/09 has been entered.

2. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

3. Claims 28-42 are pending in this application. Cancellation of claims 12-16 and 18-27 is acknowledged. Claims 1-11 and 17 stand canceled. Addition of new claims 28-42 is acknowledged.

4. Claims 28-42 are examined.

Specification

5. The use of the trademarks Instillagel, Endosgel, K-Y, and others has been noted in this application (see page 8, lines 3-8 of the specification). The trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **Claims 28-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 28 claims the use of a composition consisting essentially of the combination of a polyacrylic acid, thickener, and humectant. However, this specific combination is not specifically taught in the specification as originally filed. While the specification teaches polyacrylic acid in combination with glycerol and NaCl, and celluloses in combination with humectants and isotonicizing substances, the

specification does not specifically teach the combination of polyacrylic acid, thickener, and humectant; therefore, the subject matter constitutes new matter. If Applicant feels that the new claim is not new matter, Applicants must provide page and line number(s) where the support is found in the specification.

8. **Claims 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 30 claims that the thickener is a cellulose; however, this teaching is not found in the specification as originally filed. The specification teaches that examples of suitable organic substances with a lubricant effect include celluloses (page 6, lines 18-20), and that the compositions may include thickeners (page 6, line 8), but the specification does not teach that the thickener is a cellulose. Therefore, the claims constitute new matter.

9. **Claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 32 claims that the humectant is selected from the group consisting of propylene glycol, glycerol, and polyethylene glycol; however, this teaching is not found in the specification as originally filed. The specification teaches that examples of suitable solvents include propylene glycol and glycerol (page 5, lines 10-14), and examples of suitable organic substances with a lubricant effect include glycerol and polyethylene glycol (page 6, line 30 and page 7, line 2), and that humectants may be used in combination with celluloses (page 7, lines 21-22), but the specification does not teach that the humectants are selected from the group consisting of propylene glycol, glycerol, and polyethylene glycol. Therefore, the claims constitute new matter.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 28, 30, 32-34, and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara et al (US Patent 3,971,848, "Kasahara '848", cited in the previous Office action) in view of Van Leuven (US Patent 4,267,168, cited in the previous Office action) as evidenced by Bringloe (US Patent 4,765,478, cited in the previous Office action).

The claimed invention is drawn to a method for reducing the frictional force between an item to be delivered and a birth canal of a mother in human vaginal child birthing, which comprises introducing a composition comprising a physiologically acceptable organic lubricant consisting essentially of a polyacrylic acid; a thickener; a humectant; and no alkali metal salts of metaphosphates; in an effective amount into the birth canal of the mother, wherein said composition is in the form of a paste, gel, cream, suppository, or foam (see claim 28).

Kasahara '848 teaches a composition having lubricating property comprising fucoidin and alginic acid (abstract) and does not contain alkali metal metaphosphates. The composition may be used to lubricate the birth canal in human bodies to facilitate the delivery of the fetus (col. 5, lines 16-32). The composition may be optionally mixed with sodium polyacrylate and carboxymethyl cellulose (col. 5, lines 39-42). Kasahara '848 further teaches that the addition of sodium polyacrylate is preferable to afford lubrication at the time of parturition, and the addition of a viscous substance (i.e., a thickener) such as carboxymethyl cellulose results in a composition having a further improved lubrication (col. 2, lines 21-36), and therefore one skilled in the art would be motivated to include said substances in the composition.

While Kasahara '848 teaches the presence of a polyacrylic acid and a thickener, Kasahara '848 is silent with respect to the presence of a humectant in the composition.

Van Leuven teaches that the humectants propylene glycol and glycerine (i.e., glycerol) are used in compositions which act as lubricants to be used during delivery at the time of birth (abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add the humectants propylene glycol and/or glycerine to the composition of Kasahara '848; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the addition of said humectant(s) provides the benefits of a very soothing action on tender tissue, as with glycerin, and some bacteriocidal activity, as with propylene glycol, as taught by Van Leuven (see col. 6, lines 1-2 and col. 5, lines 47-49, respectively). One would reasonably expect success from the addition of propylene glycol and/or glycerin as taught by Van Leuven to the composition of Kasahara '848 because both references are drawn to compositions useful for lubricating the birth canal during delivery.

Regarding the form of the composition, Kasahara '848 teaches that the composition is a "mucous, thready composition having lubricating property" (col. 2, lines 7-8) and that carboxymethyl cellulose is a viscous substance (col. 2, lines 31-35), and therefore one skilled in the art would reasonably expect the composition to be in the form of a gel; as further evidence, Bringloe teaches that carboxymethyl cellulose is a known gelling agent in topical compositions (see col. 3, lines 46-53), which would also favor the formation of a gel composition.

Regarding claim 30, Kasahara '848 teaches that the viscous substance (thickener) carboxymethyl cellulose may be added to the composition.

Regarding claim 32, Van Leuven teaches the humectants propylene glycol and glycerine (i.e., glycerol) are used in compositions which act as lubricants to be used during delivery at the time of birth (abstract).

Regarding claim 33, Van Leuven teaches that the composition includes propylene glycol in the range of from about 1.2 to 2.5% (col. 5, lines 47-48). This is within Applicant's range of 0.5 to 3%.

Regarding claim 34, Kasahara '848 teaches that the composition to be used for lubricating the birth canal of humans comprises water (see col. 5, lines 21-32).

Regarding the application steps of the composition (claims 37-41), Kasahara '848 exemplify application of the composition just before parturition (col. 5, lines 27-30). The phrase "just before parturition" reasonably reads on before labor or dilation begins, as well as during the dilation phase. While Kasahara '848 is silent with respect to multiple application steps, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the composition in multiple steps, since said steps amount to design choice and within the purview of the skilled artisan.

Regarding claim 42, Kasahara '848 teaches that the composition is injected into the vagina (i.e., applied to the birth canal; see col. 5, lines 16-32) and that the substances are not likely to escape between the frictional interfaces of the animals (col. 2, lines 25-30). Therefore, one skilled in the art would reasonably expect the

composition to have a greater adhesion to the surface of the birth canal compared with the skin of the fetus.

13. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Bringloe as applied to claims 28, 30, 32-34, and 37-42 above, and further in view of JP 46-24256 ("JP '256", cited in the previous Office action).

Claim 29 of the claimed invention is drawn to the method of claim 28, wherein said polyacrylic acid is present in a concentration of from 0.25 to 5% by weight.

The invention of the combined references is delineated above (see paragraph 12).

The invention of the combined references is silent with respect to the amount of sodium polyacrylate in the composition.

JP '256 teaches that sodium polyacrylate is useful as a lubricant during birth, and that the lubricant does not lose its activity when diluted to 0.2-0.3% concentration. This amount overlaps that of the claimed invention. One skilled in the art would be motivated to manipulate the amount of sodium polyacrylate from within said ranges by routine experimentation, in order to optimize the lubricity of the resultant composition.

14. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Bringloe as applied to

claims 28, 30, 32-34, and 37-42 above, and further in view of Behl et al (US Patent 5,580,574).

Claim 31 of the claimed invention is drawn to the method of claim 30, wherein said cellulose is present in a concentration of from 1 to 3% by weight.

The invention of the combined references is delineated above (see paragraph 12).

The invention of the combined references is silent with respect to the amount of cellulose in the composition.

Behl et al teach pharmaceutical compositions for transdermal delivery (abstract). The compositions include gelling agents in amounts sufficient to obtain a desired consistency of the gel; amounts of carboxymethyl cellulose are preferably in the range of from about 2 to 5 percent by weight of the composition (col. 2, line 59 - col. 3, line 5). This amount overlaps that of the claimed invention. One skilled in the art of topical compositions would be motivated to manipulate the amount of carboxymethylcellulose taught in Kasahara '848 from within said ranges by routine experimentation, in order to optimize the desired consistency of gel as taught by Behl et al.

15. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Bringloe as applied to claims 28, 30, 32-34, and 37-42 above, and further in view of Kasahara et al (US Patent 3,814,797, "Kasahara '797", cited by Applicants in the IDS filed 7/21/04).

Claims 35 and 36 of the claimed invention are drawn to the method of claim 28, wherein between 5 to 200 mL (claim 35) or between 10 to 100 mL (claim 36) of said composition is introduced into birth canal.

The invention of the combined references is delineated above (see paragraph 12).

The invention of the combined references is silent with respect to the amount of composition introduced into the birth canal.

Kasahara '797 teaches aqueous lubricating compositions for imparting lubricity to the parts of living bodies (abstract). The aqueous compositions may be applied to human beings (col. 3, lines 50-51). For use in human delivery, Kasahara '797 exemplify an amount of 100 mL of the composition (see Example 2, column 4).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use an amount of the composition of the combined references of 100 mL; thus arriving at the claimed invention. When determining an appropriate amount, one skilled in the art would look for guidance from the teachings in the prior art of other lubricant compositions used in human delivery, such as Kasahara '797. Therefore, one skilled in the art would be motivated to select an amount of lubricating composition according to the teachings of Kasahara '797, absent evidence to the contrary.

Response to Arguments and Declaration

16. Applicant's arguments with respect to claims 12-16 and 18-27 have been considered but are moot in view of the new ground(s) of rejection. However, since the Examiner has retained the references of Kasahara '848, Van Leuven, Bringloe, and JP '256, the Examiner will respond to arguments pertaining to these references.

In response to Applicant's argument that Kasahara '848 and Bringloe do not disclose the use of a polyacrylic acid, it is noted that Kasahara '848 teach that its composition may be mixed with sodium polyacrylate, and that the addition of sodium polyacrylate is preferable to afford lubrication at the time of parturition, and therefore one skilled in the art would be motivated to include said substance in the composition.

Applicants also argue that Kasahara's composition obligatorily contains large amounts of alginates and fucoidin as organic substances having a lubricant effects. Applicants argue that addition of alginates often leads to the formation of unwanted discoloration or precipitates, as is disclosed in paragraph [0024] of post-published U.S. application serial No. 11/718,995, and therefore materially affects the basic and novel characteristics of the composition for use in the present claims.

This argument is not persuasive. Applicants are basing their argument on the use of the more restrictive bridging term "consisting essentially of", which is intended to limit the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristics of the claimed invention" (see MPEP 2111.03). However, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication **in the specification or claims**

of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355. The **instant specification** does not clearly indicate that fucoidin and alginates would materially affect the basic and novel characteristics of the claimed invention; on the contrary, the specification teaches that edible vegetable oils, fats, and waxes are examples of suitable organic substances with a lubricant effect. It is further noted that the teachings of post-published U.S. application serial No. 11/718,995 do not require that alginates be excluded from its compositions, but only that it is preferred to be free of alginates, and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Therefore, alginates and fucoidan do not materially affect the basic and novel characteristics of the claimed invention, and reasonably read on the claimed invention.

Applicants argue that the enclosed declaration signed by the inventor, Dr. Andreas Schaub, details unexpected experimental results when using the presently claimed method as well as Dr. Schaub's expert opinion regarding significant differences between animal and human delivery.

The Declaration filed 8/31/09 has been fully considered, but is not persuasive for overcoming the rejection.

In response to the Declaration's statements and evidence regarding shorter duration of labor in patients using obstetric gel of the presently claimed method when compared with labor where obstetric gel was not used (paragraphs 5 and 6 of

Declaration), said statements and evidence are not persuasive because the Declaration does not compare the claimed invention with the closest prior art of Kasahara '848, which also uses a composition to facilitate the delivery of a fetus. Additionally, Kasahara '848 clearly teaches that the delivery of a fetus is facilitated with the use of its composition (see col. 5, lines 16-32); therefore, one skilled in the art would reasonably expect the labor to not last as long, and thus shorter labor times are not unexpected.

In response to the Declaration's statements regarding "significant differences" between animal and human delivery (paragraph 7 of Declaration), said statements are not persuasive because Kasahara '848 demonstrates by example that its composition may be used in human bodies for the delivery of a fetus, without any residual side effects being observed, and therefore is useful in human bodies as well as animals (see col. 5, lines 16-32).

In response to the Declaration's statements and evidence regarding unexpected bactericidal effect of the claimed composition (paragraph 8 of Declaration), said statements and evidence are not persuasive because Van Leuven clearly teaches that the presence of propylene glycol imparts some bacteriocidal activity (see col. 5, lines 47-49), and therefore the bactericidal effect in the claimed invention is not unexpected.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. **Claims 28-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 38-42, 49-57, and 62-68 of copending Application No. 11/718,995.** Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same method steps and composition components.

The claimed invention is delineated above (see paragraph 12).

Copending application '995 claims a method for reducing the frictional force between an item to be delivered and a birth canal of a mother in human vaginal child birthing, comprising applying a composition having a lubricant effect to the birth canal of a mother, the composition comprising specific amounts of polyacrylic acid, hydroxyethyl cellulose, and propylene glycol, wherein said composition is free of alginic acid, alginates, and silver ions (see claim 41). Hydroxyethyl cellulose is a thickener, and propylene glycol is a humectant, as defined in the specification of copending application

'995 (see page 6, lines 5-10 and 20-23 of the '995 specification); therefore, the claims are drawn to the same method steps and composition components.

Regarding claim 29, copending application '995 claims 0.4 to 0.7% by weight polyacrylic acid (claim 41).

Regarding claims 30 and 31, copending application '995 claims 1 to 6% by weight hydroxyethyl cellulose (claim 41).

Regarding claim 42, copending application '995 claims propylene glycol (claim 41).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Ashwin Mehta/

Primary Examiner, Technology Center 1600